no new matter has been added for the reasons set forth below each amendment:

#### Page 2 line 15

"the patient unconscious, the length of the treatment time and course, [and] the necessarily..."

This amendment clarifies the meaning of the sentence by correcting a typographical error.

# Page 2 line 16

"large, bulky non-portable gas cylinders, and the physician administration it requires. Most..."

This amendment clarifies the meaning of the sentence by correcting a typographical error.

## Page 3 line 5

"concentrations which are <u>chronically</u> unbreathable. Other inhalation devices, systems, and methods"

This amendment clarifies the meaning of "high concentrations" and is supported by the text found on Page 6, Line 14.

# Page 8 line 16

"pure carbon dioxide or other pure therapeutic gas. By "essentially pure," it is meant that the carbon dioxide, or other..."

This amendment corrects a typographical error and is supported by the text of the next sentence.

### Page 10 line 7

"will be suitable for sealing in or against a human nostril. <u>In an alternative embodiment, the outlet</u> will be suitable for sealing in or against both human nostrils. In [an] another alternative environment, ..."

Support for this addition can be found on Page 9, Line 5 which provides for directing the therapeutic gas into both nostrils.

1

## Page 10 line 8

"the outlet will be suitable for sealing against a human mouth. In <u>yet</u> another alternative..."

This amendment corrects a typographical error.

# Page 11 line 1

"cylinder[,] that is capable of holding a volume of therapeutic gas, the adjustable flow regulator comprises a turnable cap at one end of the cylinder,..."

This amendment corrects an obvious omission regarding the nature of the cylinder and is supported by text found on Page 10, Lines 23-24.

## Page 12 line 30

"1. Treatment of Allergic Rhinitis, [and] Headache, and Other Common Ailments"

This amendment corrects an obvious omission in the title of the section which discusses other ailments in addition to allergic rhinitis and headache.

## Page 13 line 13

"bronchiolitis by inhalation of helium/oxygen mixtures. Also, inhaled <u>dilute</u> nitric oxide improves the..."

This amendment corrects obvious omissions regarding current treatments, which would have been recognized by persons of ordinary skill in the art.

### Page 13 line 34

"available immediately, upon demand by the user, at the time when [irritating] symptoms..."

This amendment clarifies that any of the disclosed symptoms, irritating or not, can be ameliorated by the application of carbon dioxide, and is supported by the text found on page 13, lines 29-30.

### Page 14 line 9

"individual user, the degree and extent of the user's [irritant reaction] symptoms, and the site of carbon..."

This amendment makes an obvious substitution and is generally supported by the text found on Page 13, lines 29-30.

#### Page 14 line 10

"dioxide [injection] <u>infusion</u>. Flows as low as 1cc/sec for 1-2 seconds into the nose are effective for..."

This amendment corrects a typographical error.

### Page 15, line 11

"the carbon dioxide, carbon dioxide is [injected] <u>infused</u> into a nostril and continued until full relief"

This amendment corrects a typographical error.

### Page 15 line 12

"is obtained. This usually occurs [when] <u>after</u> the carbon dioxide flow is detected exiting the ..." This amendment corrects a grammatical error to clarify that the relief does not end with the flow of carbon dioxide.

### Page 15 line 20

"is most effective to [inject] <u>infuse</u> the carbon dioxide through pursed lips directly into the mouth"

This amendment corrects a typographical error.

## Page 15 line 24

"rate and selectable [injection] infusion site afforded by the devices of the present invention."

This amendment corrects a typographical error.

### Page 19 line 12

"[bottle] <u>cylinder</u> 94. The seal 90 extends above a threaded neck 96 of the gas [bottle] <u>cylinder</u> 94, The lower..."

This amendment corrects an obvious inconsistency in usage, since this type of container is not a bottle, and "cylinder" is used elsewhere in the specification to refer to this type of container: e.g., Page 11, Line 1.

## Page 21 lines 11, 13

Each reference number 94 is replaced by 94'.

This amendment corrects typographical errors in the reference numbers.

## Page 21 line 15

Each reference number 96 is replaced by 96'.

This amendment corrects typographical errors in the reference numbers.

# Page 21 line 29

Add the following sentence: "Above the needle region 98' the needle may be of still larger diameter. For example, in one embodiment the needle diameter was approximately 1 mm or .04 inches."

This amendment clarifies that the needle may be larger above the second region and is supported by the drawing found on page 15 of the Provisional Application 60/143,164 which was incorporated by reference.

#### Page 22 line 16

"Embodiment with Separate Puncture and Valve [Seal Mechanism] <u>Seat Means</u>"

This amendment corrects a typographical error and makes the title consistent with the text that

follows.

# Page 23 line 5

"[bottle] <u>cylinder</u> 94. The seal 90 extends above a threaded neck 96 of the gas [bottle] <u>cylinder</u> 94, The lower..."

This amendment corrects an obvious inconsistency in usage, since this type of container is not a bottle, and "cylinder" is used elsewhere in the specification to refer to this type of container: e.g., Page 11, Line 1.

### Page 25 lines 30 & 31

"instructions will refer specifically to use of the [cartridge] <u>dispenser</u> 10 in a way to relieve symptoms of common ailments as described above. In addition to the [cartridge] <u>dispenser</u> 10 and written..."

This amendment corrects an obvious inconsistency in usage, as the reference number referred to a "dispenser" earlier in the Specification, Page 25, Line 27.

## Page 26 lines 26 & 27

Delete the last sentence of the paragraph in its entirety

This amendment corrects a clear error, as the text indicates that Figure 15 shows flow rate characteristics for both the one-piece and the two-piece embodiments. The reference to the one-piece embodiment was intended to refer to the device used in human application tests described in the next section.

#### Page 26 line 31

Insert the following sentence as the first sentence of the paragraph.

The models of the initial one-piece embodiment (test device) were used in these preliminary human application tests.

This amendment clarifies that the one-piece embodiment was used for the tests described and is supported by the text found on Page 6, Lines 31-37, and Page 7, Lines 1-7 of the Provisional

Application No. 60/143,164 filed July 12, 1999, which was incorporated by reference into the current application.

# Page 26 line 32 and page 27 line 1

"was approximately 3 to 4 inches long and 6/8 to 7/8 inches in diameter [constructed as described above]. The device consisted of a plastic twist-top flow regulator mounted on."

This amendment corrects a typographical error, as the device is described later in the paragraph, not "above."

# Page 31 line 16

"treatment had the same average [symptom] headache free efficacy of 80% (migraine=75%,..."

The amendment corrects a typographical error, removing an extraneous word.

### In the Abstract:

#### Line 8

"where the gas infuses [into] a body region in order to bathe the mucous membranes therein.

It..."

This amendment removes an extraneous word.

#### In the Drawings:

Please amend Fig.7 as indicated in red on a copy of the drawing as originally filed. This amendment corrects an obvious error, as the cross-section line 8-8 in Figure 7 does not match the cross-section shown in Figure 8.

A separate letter to the Official Draftsman is included with this Preliminary Amendment.